

Remarks

Claims 1-10, 12-22, and 24-46 were pending in the subject application. By this Amendment, claim 43 has been amended, claims 1-10, 12-17, 20-21, 24-42, and 44-46 have been cancelled, and new claims 47-53 have been added. The undersigned avers that no new matter is introduced by this amendment. Accordingly, claims 18, 19, 22, 43, and 47-53 are currently before the Examiner for consideration. Early and favorable consideration of the pending claims is respectfully requested.

As an initial matter, the applicants and the applicants' representative wish to thank Examiner Sullivan and Examiner Falk for the courtesy of the telephonic interviews conducted with the undersigned on October 31, 2003 and December 3, 2003, regarding the rejections under 35 U.S.C. §112, first paragraph, and claims 43-46. The remarks and amendments set forth herein are consistent with the substance of those interviews and are believed to address the outstanding issues as discussed during the interviews.

The applicants gratefully acknowledge the Examiner's withdrawal of the rejection under 35 U.S.C. §112, second paragraph and 35 U.S.C. §102(a) (over Mucke *et al.*). The applicants also gratefully acknowledge the Examiner's indication that claims 18, 19, and 22 are allowable.

As indicated above, the applicants have amended claim 43 and added claims 47-53. Support for these amendments and new claims can be found, for example, at page 8, lines 17-33; page 9, lines 1-10; pages 12-14; page 15, lines 8-16 and 25-32; page 17, lines 22-32; and Examples 1-3 at pages 25-39 of the specification, as well as the claims, as originally filed (page 7, lines 5-29; pages 11-12; page 13, lines 18-25; page 14, lines 3-9; and pages 31-36 of the substitute specification).

Claims 1-10, 12-17, 24-43, and 46 are rejected under 35 U.S.C. § 112, first paragraph, as lacking sufficient written description. In addition, claims 1-10, 12-17, and 24-46 are rejected under 35 U.S.C. §112, first paragraph, as non-enabled by the subject specification. The applicants respectfully submit that the claimed invention is sufficiently described and enabled by the subject specification. However, by this Amendment, the applicants have cancelled claims 1-10, 12-17, 24-42, and 44-46. Claim 43 has been amended to recite that the transgene comprises a nucleic acid sequence encoding alpha-1-antichymotrypsin (ACT) operably linked to a glial fibrillary acid protein (GFAP) promoter, wherein when the transgenic mouse is crossed with a second transgenic mouse

whose genome comprises a nucleic acid sequence encoding an amyloid precursor protein (APP) V717 mutant or whose genome is homozygous for a non-functional apolipoprotein (ApoE) gene, progeny are produced having an increased rate or extent of amyloid formation within the brain tissue. New claims 47-52 pertain to the GFAP promoter, the expression site of the nucleic acid sequence encoding ACT, the APP V717 mutant, and the ApoE gene. Claim 53 is directed to a transgenic mouse having a transgene comprising a nucleic acid sequence encoding alpha-1-antichymotrypsin (ACT) operably linked to a glial fibrillary acid protein (GFAP) promoter, wherein the genome further comprises a second transgene encoding the APP V717 mutant or is homozygous for a non-functional ApoE gene, or both, and wherein the transgenic mouse has an increased rate or extent of amyloid formation within the brain tissue. As indicated at pages 5 and 8 of the outstanding Office Action, the subject specification sufficiently describes and enables transgenic animals comprising the alpha-1-antichymotrypsin transgene under the transcriptional control of the GFAP promoter, optionally including a second transgene encoding the hAPP (V717f) protein, either with or without a functional endogenous ApoE gene, and having a phenotype of exacerbated β -amyloidosis. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 1, 5, 6, 8, 29, 31, 35, 36, and 38 are rejected under 35 U.S.C. §102(b) as being anticipated by either Yeung *et al.* (*J. Cell. Biochem. Suppl.*, 1994, 0:164) or Kuljis *et al.* (*Soc. Neurosci. Abstr.*, 1993, 19:1035). Claims 20 and 21 are also rejected under 35 U.S.C. §102(b) as being anticipated by Kobayashi *et al.* (*Neurosci. Lett.*, 1994, 172:147-150). Claims 24-26 are rejected under 35 U.S.C. §102(b) as being anticipated by Snow *et al.* (WO 97/46664) as evidenced by Anger *et al.* (*Neurotoxicol.*, 1991, 12:403-413). In addition, claims 1, 7, 10, 12, 13, 15-17, 29, and 41 are rejected under 35 U.S.C. §103(a) as being obvious over Yeung *et al.* or Kuljis *et al.*, in view of Snow *et al.* The applicants respectfully submit that the rejected claims are not anticipated by, or obvious over, the cited references. However, by this Amendment, the applicants have cancelled claims 1, 5, 6, 7, 8, 10, 12, 13, 15-17, 20, 21, 24-26, 29, 31, 35, 36, 38, and 41, rendering the rejections under 35 U.S.C. §102(b) and §103(a) moot.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

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The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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